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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/828,539 | 04/04/2001 | Howard Preissman | 361722000201 | 9912 |

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| EXAMINER |
|---|
| MILLER, CHERYL L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3738 | |

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/828,539 | PREISSMAN, HOWARD | |
| | Examiner | Art Unit | |
| | Cheryl L. Miller | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 December 2001 and 02 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Response to Arguments*

*1.* Applicant's arguments with respect to claims 33-41 have been considered but are moot in view of the new ground(s) of rejection. The previous office action has been withdrawn in view of the preliminary amendment that crossed in the mail.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 44 and 45 recite the limitation "The injectable composition of claim 40" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "The injectable composition" to recite --The enhanced visibility composition--.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (USPN 5,258,028). Ersek discloses an enhanced visibility composition that includes all limitations recited in the claims. Ersek discloses a flowable matrix (31) and radiopaque particles (30), (col.3, lines 7-8, 15-18; col.10, lines 23-26) having a size between 350μ and 2200μ, 570μ and 2200μ, 450μ and 1600μ, or 570μ and 1150μ (col.5, lines 43-45), and further having smaller particles having a size between 120μ and 350μ (col.5, line 64-col.6, line 2).

6. Claims 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lawin et al. (USPN 5,451,406, cited by applicant in IDS). Lawin discloses an enhanced visibility composition that includes all limitations recited in the claims. Lawin discloses a flowable matrix (col.1, lines 58-59; col.2, lines 24-36) and radiopaque particles (col.1, lines 56-58; col.2, lines 8-19, 46-50), having a size between 350μ and 2200μ, 570μ and 2200μ, 450μ and 1600μ, or 570μ and 1150μ (col.1, lines 60-62).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 33-39 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draenert et al. (USPN 6,080,801, cited by applicant in IDS) in view of Ersek et al. (USPN 5,258,028). Referring to claim 33, Draenert discloses a composition comprising a biocompatible matrix (col.3, lines 22-29), radiopaque particles, and a liquid contrast agent (liquid and/or solid contrast agents, col.3, lines 58-64). Draenert does not disclose however, particles having a size of 120μ to 2200μ, nor does Draenert disclose a composition that is injectable. Ersek teaches radiopaque particles having an increased size of 120μ to 2200μ, in order to optimize the size for aiding in injection, and avoiding the adverse effects of smaller particles (col.3, line 60-col.4, line 44; col.6, lines 8-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the radiopaque particles of Draenert with the radiopaque particles having the increased size taught by Ersek, in order optimize size to aid in injection, and avoid adverse effects of smaller particles.

Referring to claim 34, Draenert discloses matrix and particles forming a slurry (admixture, col.2, line 50; col.4, lines 38-44).

Referring to claim 35, Draenert discloses a mixture of matrix and particles forming a hard tissue implant (col.1, lines 18-24).

Referring to claims 36-39, Ersek teaches particles having a size of between 350μ and 2200μ, 570μ and 2200μ, 450μ and 1600μ, or 570μ and 1150μ (col.5, lines 43-45) for the reasons above, and further having smaller particles having a size between 120μ and 350μ in order to provide variation in size to take into account normal variation from patient to patient so that the composition may be used with all patients (col.5, line 64-col.6, line 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Draenert's composition having radiopaque particles, with Ersek's teaching of optimal particle size with particle variation, in order to provide smaller and larger particles in order to account for normal variation from patient to patient, so that the composition may be used with all patients.

9. Claims 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooke et al. (USPN 5,336,699, cited by applicant in IDS) in view of Ersek et al. (USPN 5,258,028). Referring to claims 47 and 49-53, Cooke discloses an injectable composition (col.8, lines 28-31) comprising a hard tissue implant biocompatible matrix (col.2, lines 58-61) and radiopaque particles mixed within the matrix (col.1, lines 18-19). Cooke does not disclose however, particles having a size between 120μ and 2200μ, 350μ and 2200μ, 450μ and 1600μ, 570μ and 1150μ, and additional particles having a size between 120μ and 350μ or up to 350μ. Ersek teaches radiopaque particles having a size between 120μ and 2200μ, 350μ and 2200μ, 450μ and 1600μ, 570μ and 1150μ, and additional particles having a size between 120μ and 350μ or up to 350μ in order to increase the size (optimizing), which in turn aids in injection, and avoids the adverse effects of smaller particles (col.3, line 60-col.4, line 44; col.6, lines 8-12) and provides variation in size taking into account normal variation from patient to patient (col.5, line 64-col.6, line 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the radiopaque particles of Draenert with the radiopaque particles having the increased size and size

variation taught by Ersek, in order optimize size, aid in injection, avoid adverse effects of smaller particles and with Ersek's teaching of, and provide smaller and larger particles in order to account for normal variation from patient to patient, so that the composition may be used with all patients.

Referring to claim 48, Cooke discloses a matrix and particles forming a slurry (intermixed, col.8, lines 65-69; col.4, lines 55-60).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl Miller
October 15, 2002

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700